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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

CHORBAJI, M

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 07/16/01

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/259,758

Applicant(s)

BROWN-SKROBOT ET AL.

Examiner

MONZER R CHORBAJI

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

RESPONSE TO THE AMENDMENT DATED 4/20/01

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claims 1-3, 5-6, 10, 16, 18, 20-27, 29, 31-33, 37, and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 3, applicant uses parenthesis for the range of the UV radiation "(240-280 NM)". Also, applicant uses parenthesis for *Bacillus Stearothermophilus* "(ATCC 7953)". It would be clearer for example to use the following: in the range of 240 to 280 NM in the above mentioned claims.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (U.S.P.N. 5,786,598) in view of.

With respect to claims 1-19, Clark et al teaches a process and an apparatus for sterilizing a medical device (col.1, lines 7-20) comprising the following concepts: subjecting a medical device (col.1, lines 13-15) to UV radiation (col.3, lines 60-62) in the range of 240-280 NM (col.3, line 3) using energy value at least 3.9 mj/cm^2 (col.8, lines 10-12). In addition; Clark et al teaches a sterility assurance level of at 10^{-6} (abstract, line 21). Furthermore; all the energy values in the claims fall within the teaching of Clark et al energy value range (col.8, lines 10-12) which contains a specific low range value and a specific high range value. Clark et al goes on to further teach of specific energy values within this range (col.8, lines 11-12). Moreover; Clark et al discloses the following concepts: the application of UV radiation to spores (col.9, lines 50-53);

the usage of at least one pulsed radiation source (col.6, line 26 and col.3, lines 51-56; various time ranges for applying the radiation which all the values in the claim falls into (col.8, lines 12-19); more than 1 radiation source (col.6, line 26); radiation sources pulse substantially simultaneously (col.10, lines 35-37, since the reference establishes multiple flash lamps using time ranges which encompass all the time values of the claims); flash lamps comprises a reflector and a lamp (figure 1, 22) wherein the fluence of each is at the focal plane of reflector (figure 1, 22:20); pulsed radiation source in at most three pulses (col.9, lines 62-67 and col.10, lines 33-37); wherein the medical device is in a container (col.4, lines 55-57); container does have a transmissivity to UV radiation but no specific value was suggested (col.4, lines 30-32); medical device is a contact lens (col.4, lines 55-57); contact lens blocks at least 50% of the UV radiation (col.4, lines 16-17, since the contact lens transmits more than about 1% which is equivalent to blocking UV radiation to at least 50%); and container comprises an aqueous solution (col.8, line 4).

With respect to claims 1-19, Clark et al does not teach the following concepts: D values specific for *Bacillus Stearothermophilus* ATCC 7953; radiation is produced by a laser; determining the D value of *Bacillus Stearothermophilus* ATCC 7953 by a mathematical relationship; and a specific transmissivity value for the container. However; Clark et al does provide examples of applying UV radiation to various types of spores (examples 1 and 2)

wherein the D values of the spores is inherently represented by achieving a sterility of assurance level of at least 10^{-6} .

With respect to claims 20-41, Clark et al teaches a process and an apparatus for sterilizing a medical device (col.1, lines 7-20) comprising the following concepts: modifying radiation from a radiation source to eliminate wavelengths which would damage medical device (col.3, line 36 and line 38); medical device is in a hermetically sealed container (col.8, lines 37-39); container comprises a non-preserved aqueous solution (col.1, lines 10-13); container is transmissive to radiation in substantially all directions (col.6, lines 45-55); the use of packages or containers is disclosed made of thermoplastics (col.3, line 48 and col.1, lines 29-30); at least one flash lamp containing a rare gas as a luminous component (col.10, lines 20-25); an apparatus is light-tight (col.8, lines 38-39); and forming a contact lens (col.5, lines 43-61).

With respect to claims 20-41, Clark et al does not teach the following concepts: D values specific for *Bacillus Stearothermophilus* ATCC 7953; radiation is produced by a laser; determining the D value of *Bacillus Stearothermophilus* ATCC 7953 by a mathematical relationship; a specific transmissivity value for the container; and container comprises a lid and a bowl.

With respect to claims 42-50, Clark et al teaches a process and an apparatus for sterilizing a medical device (col.1, lines 7-20) comprising the following concepts: at least one reflector directs radiation from each radiation source to a treatment area (figure 1, 18:22); treatment area is located at the focal plane of reflector (figure 8, 18:22 and the unlabeled rays); reflectors have

enhanced reflection (col.6, lines 42-44); and the reflector minimizes the non-ultraviolet radiation reaching the medical device (col.6, lines 45-48). In addition; Clark et al teaches of a capacitance and a potential (col.10, lines 1-8), however; Clark et al does not provide specific values for capacitance and for potential. Since the claims are trying to exactly accomplish what Clark et al teaches then it is inherent in the apparatus of Clark et al to encompass the same values for capacitance and a potential.

With respect to claims 42-50, Clark et al does not teach the following concepts: D values specific for *Bacillus Stearothermophilus* ATCC 7953; radiation is produced by a laser; determining the D value of *Bacillus Stearothermophilus* ATCC 7953 by a mathematical relationship; a specific transmissivity value for the container; container comprises a lid and a bowl; specific range values for capacitance and for potential; and radiation sources are wired in series.

With respect to claims 1, and 15-16, Matner et al teaches of a method for determining the efficacy of a sterilization cycle (col.1, lines 7-8) wherein it is known to use *Bacillus Stearothermophilus* ATCC 7935 to verify how efficient a sterilization cycle is (col.2, lines 35-39).

Matner et al does not teach the following: D values specific for *Bacillus Stearothermophilus* ATCC 7953; forming contact lens; radiation is produced by a laser; determining the D value of *Bacillus Stearothermophilus* ATCC 7953 by a mathematical relationship; a specific transmissivity value for the container;

container comprises a lid and a bowl; specific range values for capacitance and for potential; and radiation sources are wired in series.

With respect to claims 1, and 15-16, Shalaby et al teaches of methods of sterilization comprising, col.2, lines 20-22; radiation source, col.2, lines 20-48; wherein the concept of D-value is and its importance to sterility assurance level is explained, col.3, lines 28-65; also the D-values of *Bacillus Stearothermophilus* are shown, columns 6-11 (examples 1-6). Furthermore; Shalaby teaches of known mathematical relationship between transmissivity, and D-values, col.3, lines 46-57.

Shalaby et al does not teach the following: radiation is produced by a laser; a specific transmissivity value for the container; container comprises a lid and a bowl; specific range values for capacitance and for potential; and radiation sources are wired in series.

With respect to claims 13, 16, 31-33, 44-45, and 47, Dunn et al teaches of a method for sterilizing packaging of medical devices (col.1, lines 17-21) wherein a laser is used (col.2, lines 17-22); a container with at least 50% transmissivity to UV light is used (col.6, lines 15-20); and specific range values for capacitance and for potential (col.22, lines 23-25); and radiation sources are wired in series (figure 3, 358).

Dunn et al does not teach of container comprising a lid and a bowl.

With respect to claim 33, Heyl et al teaches of a method for sterilizing and disinfecting, col.1, lines11-16, wherein the container comprises a lid and a bowl, col.9, lines 35-37.

Thus, it would have been obvious and one having ordinary skill in the art would have been motivated to combine the teaching of Clark et al for a system and a method of sterilizing a medical device by applying UV radiation to spores with another art-known in the determining the efficacy of sterilization cycles by specifically using *Bacillus Stearothermophilus* (ATCC 7935) bacterial spore for the known and expected results that the bacterial spore is recognized as the most resistant form of bacterial life and further all tests for determining sterilization efficacy use it.

Response to Arguments

6. Applicant's arguments filed 04/20/01 have been fully considered but they are not persuasive.

With respect to "Hindsight reconstruction of references". The claims are accomplishing what Clark et al has accomplished. All prior arts used are in the art of sterilizing medical devices.

With respect to "Clark does not teach nor suggest D values". Clark et al does accomplish certain level of sterility that inherently encompasses the concept of D values.

With respect to "Clark does not teach any minimum energies to achieve sterility". Clark et al teaches a minimum energy value of 0.01 j/cm^2 .

Furthermore; Clark et al uses a specific value of energy in example 2 (col.11, line

60). In addition; Clark et al teaches a value of the total energy applied of which UV radiation constitutes (col.10, line 31).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MONZER R CHORBAJI whose telephone number is (703) 305-3605. The examiner can normally be reached on M-F 8:30-5:00.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ROBERT J WARDEN can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-7719 for After Final communications.

9. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Monzer R. Chorbaji *MRU*
Patent Examiner
AU 1744
June 18, 2001

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